

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

RECEIVED

AUG 14 2002

Atty Dkt. No.: CELL-017

USSN: 09/814,357

TECH CENTER 1600/2900
CERTIFICATE OF FACSIMILE

I hereby certify that this correspondence is transmitted by facsimile to the USPTO, (703) 308-4556, addressed to the Assistant Commissioner for Patents, Washington, DC 20231 on this date: August 14, 2002.

Typed or Printed Name	Susan M. Alessi		
Signature	<i>Susan M. Alessi</i>	Date	August 14, 2002
Supplemental Amendment Address to: Assistant Commissioner for Patents Washington, D.C. 20231	Attorney Docket	CELL-017	
	First Named Inventor	YU et al.	
	Application Number	09/814,357	
	Filing Date	March 21, 2001	
	Group Art Unit	1635	
	Examiner Name	Whiteman, Brian A.	
Title:		METHODS OF TREATING NEOPLASIA WITH COMBINATION OF TARGET CELL-SPECIFIC...	

Sir:

Prior to examination of the above captioned application, please make the following amendments.

IN THE CLAIMS

Please replace the pending claims with the claims below. Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment; captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Cancel claims 1-58.

Add the following new claims:

~~59.~~ A method for suppressing tumor growth in an individual comprising: administering a target cell-specific adenovirus vector, said vector comprising an adenoviral early gene essential for replication under transcriptional control of a target cell-specific transcriptional regulatory element (TRE), selected from the group consisting of a prostate-specific antigen (PSA)-TRE, an α -fetoprotein (AFP)-TRE and a human uroplakin II (UPII)-TRE and at least one antineoplastic agent selected from the group consisting of paclitaxel, docetaxel, doxorubicin and cisplatin, wherein the amount of antineoplastic agent administered is less than that known in the art to be effective for suppressing tumor growth when administered alone

Atty Dkt. N. : CELL-017

USSN: 09/814,357

60. The method of claim 59, wherein said at least one antineoplastic agent is doxorubicin.

61. The method of claim 59, wherein said at least one antineoplastic agent is cisplatin.

529
62. A method for suppressing tumor growth in an individual comprising: administering a target cell-specific adenovirus vector, said vector comprising an adenoviral gene essential for replication under transcriptional control of a prostate-specific antigen (PSA)-TRE and at least one antineoplastic agent selected from the group consisting of etoposide, estramustin and 5-fluorouracil (5-FU), wherein the amount of antineoplastic agent administered is less than that known in the art to be effective for suppressing tumor growth when administered alone.

63. The method of claim 59, wherein said at least one antineoplastic agent is selected from the group consisting of paclitaxel, docetaxel and etoposide.

64. The method of claim 59, wherein said at least one antineoplastic agent is 5-fluorouracil (5-FU).

65. The method of claim 59, wherein said at least one antineoplastic agent is doxorubicin or mitoxantrone.

66. The method of claim 59, wherein said at least one antineoplastic agent is estramustine or cisplatin.

67. A method for suppressing tumor growth in an individual comprising: administering a target cell-specific adenovirus vector, said vector comprising an adenoviral gene essential for replication under transcriptional control of an α -fetoprotein (AFP)-TRE and at least one antineoplastic agent selected from the group consisting of paclitaxel, docetaxel, doxorubicin, cisplatin, mitomycin C, and mitoxantrone, wherein the amount of antineoplastic agent administered is less than that known in the art to be effective for suppressing tumor growth when administered alone.

68. The method of claim 67, wherein said at least one antineoplastic agent is paclitaxel or docetaxel.

69. A method for suppressing tumor growth in an individual comprising: administering a target cell-specific adenovirus vector, said vector comprising an adenoviral gene essential for replication under transcriptional control of a human uroplakin II (UPII) transcriptional regulatory element

Atty Dkt. No.: CELL-017

USSN: 09/814,357

(TRE), and at least one antineoplastic agent selected from the group consisting of paclitaxel, docetaxel, doxorubicin and cisplatin, wherein the amount of antineoplastic agent administered is less than that known in the art to be effective for suppressing tumor growth when administered alone.

70. The method of claim 69, wherein said at least one antineoplastic agent is paclitaxel or docetaxel.

~~71. A method for suppressing tumor growth in an individual comprising: administering a target cell-specific adenovirus vector, said vector comprising an adenoviral gene essential for replication under transcriptional control of a prostate-specific antigen (PSA)-TRE or an α -fetoprotein (AFP)-TRE, together with mitoxantrone, wherein the amount of mitoxantrone administered is less than that known in the art to be effective for suppressing tumor growth when administered alone.~~

D 72. The method of claim 59, wherein the adenoviral early gene is E1A.

73. The method of claim 59, wherein the adenoviral early gene is E1B.

74. The method of claim 73, wherein E1B has a deletion of the 19-kDa region.

~~75. A method for suppressing tumor growth in an individual comprising: administering a target cell-specific adenovirus vector, said vector comprising an adenoviral gene essential for replication under transcriptional control of a target cell-specific transcriptional regulatory element (TRE), selected from the group consisting of a prostate-specific antigen (PSA)-TRE, an α -fetoprotein (AFP)-TRE and a human uroplakin II (UPII)-TRE and administering an effective amount of an appropriate course of external radiation therapy to the individual wherein the amount of radiation administered is less than that known in the art to be effective for suppressing tumor growth when administered alone.~~

76. The method of claim 77, wherein said TRE is a prostate-specific antigen (PSA)-TRE.

REMARKS

Claims 1-58 are canceled, and new claims 59-76 added. The new claims clarify the subject matter of the invention, and find basis in the originally filed claim set. No new matter is added.

Applicants submit that all of the claims are now in condition for allowance, which action is requested. If the Examiner finds that a Telephone Conference would expedite the prosecution of this application, he is invited to telephone the undersigned at the number provided.

FAX RECEIVED
AUG 15 2002 **OFFICIAL**

Please type a plus sign (+) inside this box →

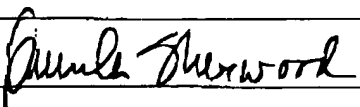
GROUP 1600

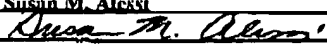
PTO/SB/21 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<h1 style="text-align: center;">TRANSMITTAL FORM</h1> <p style="text-align: center;">(to be used for all correspondence after initial filing)</p>		Application Number	09/814,357	
		Filing Date	March 21, 2001	
		First Named Inventor	YU, DE-CHAO	
		Group Art Unit	1635	
		Examiner Name	WHITEMAN, BRIAN	
Total Number of Pages in This Submission		11	Attorney Docket Number	CELL-017
ENCLOSURES (check all that apply)				
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Supplemental Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Documents <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____		
		<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Apparatus Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 1. Fax Cover Sheet		
		Remarks		
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT				
Firm or Individual Name	PAMELA J. SHERWOOD, Reg. No. 36,677			
Signature				
Date	August 14, 2002			

CERTIFICATE OF FACSIMILE TRANSMISSION		
I hereby certify that this correspondence is being facsimile filed under 37 C.F.R. §§ 1.8(d) and 1.8(a)(1)(b) addressed to: Commissioner for Patents, Washington, DC 20231 on this date: August 14, 2002.		
Typed or printed name	Susan M. Alexi	
Signature		Date August 14, 2002

Burden Hour Statement: This form is estimated to take .2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

CERTIFICATE OF TRANSMISSION			
I hereby certify that this correspondence is being transmitted by facsimile transmission to the United States Patent and Trademark Office on the date indicated below and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231. Facsimile No.: (703) 308-4556			
Typed or Printed Name	Susan M. Alessi		
Signature	<i>Susan M. Alessi</i>	Date	August 14, 2002

FACSIMILE TRANSMITTAL
BOZICEVIC, FIELD & FRANCIS LLP

200 Middlefield Road
Suite 200
Menlo Park, California 94025
Telephone (650) 327-3400
Facsimile (650) 327-3231

FAX RECEIVED

AUG 15 2002

GROUP 1600

Date: August 14, 2002

To: **PLEASE DELIVER TO**
EXAMINER BRIAN A. WHITEMAN

OFFICIAL

Facsimile No.: (703) 308-4556

From: Susan M. Alessi assisting
Pamela J. Sherwood, Ph.D.

Re: U.S. Patent Application No. 09/814,357
Title: METHODS OF TREATING NEOPLASIA WITH
COMBINATION OF TARGET-CELL SPECIFIC
ADENOVIRUS, CHEMOTHERAPY AND RADIATION
Inventor(s): YU et al.
Attorney Docket No.: CELL-017

Attached:

- Transmittal (1 page)
- Fac Transmittal in Duplicate (2 pages)
- Supplemental Amendment (7 pages)

If there are any problems concerning the transmission for these documents please contact Susan M. Alessi at (650) 833-7714 or Via email at alessi@bozpat.com.
Thanks You!

Total number of pages, including this cover sheet: 11

WARNING: This facsimile message and accompanying documents are intended only for the use of the addressee indicated above. Information that is privileged or otherwise confidential may be contained therein. If you are not the intended recipient, you are hereby notified that any dissemination, copying, review or use of the above message or the accompanying documents is strictly prohibited. If you have received this message in error, please notify us immediately by telephone or facsimile, and mail the original to us at the above address. Thank you.

RECEIVED

PTO/SB/17 (10-01)

Approved for use through 10/31/2002, OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

AUG 14 2002
TECH CENTER 1500/2900**FEE TRANSMITTAL**
for FY 2002

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT(\$)**84.00****Complete If Known**

Application Number	09/814,357
Filing Date	March 21, 2001
First Named Inventor	YU, DE-CHAO
Examiner Name	WHITEMAN, BRIAN
Group Art Unit	1635
Attorney Docket No.	CELL-017

METHOD OF PAYMENT

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit overpayments to:
 Deposit Account Number **50-0015**
 Deposit Account Name **Bozicevic, Field & Francis LLP**
☒ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17
☒ Applicant Claims small entity status. See 37 CFR 1.27

2. ☐ Payment Enclosed:
☐ Check ☐ Credit Card ☐ Money Order ☐ Other
FEE CALCULATION**2. BASIC FILING FEE**

Large Entity Fee Code	Small Entity Fee Code	Fee Description	Fee Paid
101 740 201 370		Utility filing fee	
106 330 206 165		Design filing fee	
107 510 207 255		Plant filing fee	
108 740 208 370		Reissue filing fee	
114 160 214 80		Provisional filing fee	

SUBTOTAL (1)**1. EXTRA CLAIM FEES**

Total Claims	Extra Claims	Fee from below	Fee Paid
18-20**	= 2	x 42.00	= 84.00

Large Entity Fee Code	Small Entity Fee Code	Fee Description
103 10 203 9		Claims in excess of 20
102 84 202 42		Independent claims in excess of 3
104 280 204 140		Multiple dependent claim, if not paid
109 84 209 42		** Reissue independent claims over original patent
110 18 210 9		** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) \$ 84.00

**or number previously paid, if greater; For Reissues, see above.

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity Fee Code	Small Entity Fee Code	Fee Description	Fee Paid
105 130 205 65		Surcharge - late filing fee or oath	
127 50 227 25		Surcharge - late provisional filing fee or cover sheet	
139 130 139 130		Non-English specification	
147 2,520 147 2,520		For filing a request for <i>ex parte</i> reexamination	
112 920 112 920		Requesting publication of SIR prior to Examination action	
113 1,840 113 1,840		Requesting publication of SIR after Examiner action	
115 110 215 55		Extension for reply within first month	
116 400 216 200		Extension for reply within second month	
117 920 217 480		Extension for reply within third month	
118 1,440 218 720		Extension for reply within fourth month	
125 1,960 228 980		Extension for reply within fifth month	
119 320 219 160		Notice of Appeal	
120 320 220 160		Filing a brief in support of an appeal	
121 280 221 140		Request for oral hearing	
138 1,510 138 1,510		Petition to institute a public use proceeding	
140 110 240 55		Petition to revive - unavoidable	
141 1,280 241 640		Petition to revive - unintentional	
142 1,280 242 640		Utility issue fee (or reissue)	
143 460 243 230		Design issue fee	
144 620 244 310		Plant issue fee	
122 130 122 130		Petitions to the Commissioner	
123 50 123 50		Processing fee under 37 CFR 1.17(q)	
126 180 126 180		Submission of Information Disclosure Stmt	
581 40 581 40		Recording each patent assignment per property (times number of properties)	
146 740 246 370		For each additional invention to be examined (37 CFR § 1.129(a))	
149 740 249 370		For each additional invention to be examined (37 CFR § 1.129(b))	
179 740 279 370		Request for Continued Examination (RCE)	
169 900 169 900		Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)**SUBMITTED BY**

Name (Print/Type)	Pamela J. Sherwood	Registration No. (Attorney/Agent)	38,677	Telephone	(650) 327-3400
Signature	<i>Pamela J. Sherwood</i>	Date	08/14/2002		

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.